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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	10/670,046
Filing Date	September 24, 2003
First Named Inventor	Frank Hardt
Art Unit	1771
Examiner Name	Daniel R. Zirker
Attorney Docket Number	RO0233US.CON (#90568)

Total Number of Pages in This Submission

ENCLOSURES (Check all that apply)

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation
- ☐ Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☒ Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) (please Identify below):

return postcard receipt

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	D. Peter Hochberg Co., L.P.A.		
Signature	Sean F. Mellino		
Printed name	Sean F. Mellino		
Date	7/2/07	Reg. No.	48,817

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Signature	Sean F. Mellino		
Typed or printed name	Sean F. Mellino	Date	07/02/2007

PTO/SB/17 (06-07)
Approved for use through 06/30/2007. OMB 0651-0032
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Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL For FY 2007

JUL 0 5 2007

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT	($)	0.00

Complete if Known	
Application Number	10/670,046
Filing Date	September 24, 2003
First Named Inventor	Frank Hardt
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Art Unit	1771
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FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
		Small Entity		Small Entity		Small Entity	
Application Type	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fees Paid ($)
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims	Extra Claims	Fee ($)	Fee Paid ($)
_____ - 20 or HP =	_____	x _____	= _____

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims	Extra Claims	Fee ($)	Fee Paid ($)
_____ - 3 or HP =	_____	x _____	= _____

HP = highest number of independent claims paid for, if greater than 3.

Multiple Dependent Claims	
Fee ($)	Fee Paid ($)
_____	_____

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee ($)	Fee Paid ($)
_____ - 100 =	_____	/ 50 = _____ (round up to a whole number)	x 250.00	= 0.00

4. OTHER FEE(S)

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	
Other (e.g., late filing surcharge): _____	

SUBMITTED BY

Signature		Registration No. (Attorney/Agent) 48,817	Telephone 216-771-3800
Name (Print/Type)	Sean F. Mellino		Date

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7/2/07 (Monday)
Date

Sean F. Mellino

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Frank Hardt & Paul Genich
Serial No.	:	10/670,046 / Conf. No. 5022
Filing Date	:	September 24, 2003
Examiner / Group Art Unit	:	Daniel R. Zirker / 1771
Title	:	Method for Producing Adhesive Blanks From and Endless Band and Blanks Obtained According to Said Method
Attorney File	:	RO0233US.CON (#90568)
Technology Center	:	1700

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REPLY BRIEF

Dear Sir:

This reply brief is in response to the Examiner's Answer which was mailed on May 1, 2007 in response to the Applicant's Revised Appeal Brief filed on December 27, 2006.

STATUS OF CLAIMS:

Claims 1-8 are pending in the application. Claim 9 has been canceled. The rejection of claims 1-8 is being appealed.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL:

The following issues are present in the present appeal:

1. Was the rejection of claims 1-8 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention proper?

2. Was the rejection of claims 1-8 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement proper?

3. Was the rejection of claims under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,244,677 (Kreckel *et al.*) proper?

ARGUMENT:

The rejection of claims 1-8 under 35 U.S.C. 112, second paragraph, as failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention, the rejection of claims 1-8 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, and the rejection of claims 1-8 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,244,677 (Kreckel *et al.*) are improper and should be reversed.

The Examiner first states in the Final Office action dated November 8, 2005, on page 2, that claims 1-8 fail to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The Examiner, in particular, states that the language of claim 1 which reads "the matrix layer can be a compacted material" is vague, indefinite and confusing since the specification contains no suitable teaching as to just what constitutes a "compacted material." In the Examiner's Answer (page 3), the Examiner states that the application contains no teachings (with the cancellation of former claim 9) as to just what constitutes a "compacted material" and that in paragraph [0031] the specification recites only that the matrix material can be a "compacted material, foam, fabric, porous sheet, nonwoven fabric, etc." which provides no guidance as to what a "compacted material" can comprise.

The Examiner next states in the Final Office action on page 3 that claims 1-8 are rejected as failing to comply with the enablement requirement in that the claims contain subject matter which was not described in the specification in such a way to enable one skilled in the art to make and/or use the invention. In particular, the Examiner argues that the specification provides no guidance as to what constitutes a "compacted material," but

that it only provides a discussion of the equivalence of a compacted material being a foam, fabric, porous sheet or non-woven fabric.

Lastly, the Examiner states in the Final Office action (on pages 3-4) that claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kreckel, et al. With reference to the initial Office action dated June 15, 2005, the Examiner argues that Kreckel, et al. teach a substantial anticipation of the claimed invention, disclosing an adhesive punchout article comprising an adhesive layer with an inner recess, the outer line of the adhesive punchout sharing no common point with the outline of the inner recess. The Examiner also states that the reference discloses an adhesive backed medicine pill die cut for application to the skin. The Examiner acknowledges that the reference fails to disclose the presence of any specific pharmaceutical active ingredients, such as those set forth in claim 1. However, the Examiner argues that the presence of almost any other pharmaceutical active ingredient would be an obvious modification to one of ordinary skill in the art, absent unexpected results. In the final Office action, the Examiner further argues that the specification either appears to give no meaningful guidance as to what a compacted material can be made from, or alternatively, claim 9 (now canceled) at least appeared to have formerly taught that it can be, e.g., a foam material. In the former instance, the Examiner states the reference teaches a "matrix layer," and in the latter instance, the Examiner states that the reference teaches a foamed material which it calls the carrier layer.

The Applicants again respectfully traverse the rejections discussed above, including that the claims are indefinite for failing to particularly point out and distinctly claim the subject matter. The Applicants respectfully submit that, as noted earlier, the

Examiner's focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph, is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available. The Examiner should allow claims which define the patentable subject matter with a reasonable (emphasis provided) degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of: (A) the content of the particular application disclosure; (B) the teachings of the prior art; and (C) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. (M.P.E.P. Section 2173.02, Ex. E). In particular, the Applicants respectfully submit that one having the ordinary level of skill in the art would readily recognize what a compacted material is.

The Applicants also again respectfully traverse the rejection on the basis that the claims fail to comply with the enablement requirement as not having the subject matter described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. For the reasons set forth above, the Applicants respectfully reassert the position that one skilled in the art would readily recognize what a compacted material is. Moreover, the specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available to the public. *In re Buchber*, 929 F.2d 660, 661, 18 USPQ2d 1331,

1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied,* 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984); M.P.E.P. Section 2164.05(b) (Exhibit F).

The Applicants also respectfully traverse the rejection of claims 1-8 as being obvious in light of the cited prior art.

Present claim 1 recites an adhesive die-cut article having an external contour comprising an adhesive layer with an internal cut-out having a contour, wherein the external contour of the adhesive die-cut article has no common point with the contour of the internal cut-out. The adhesive die-cut article has a matrix layer having an internal cut-out which is congruent with the internal cut-out in the adhesive layer, and matrix layer is a compacted material. A covering film covers the composite of matrix layer, adhesive layer, and internal cut-out, and the internal cut-out is filled with a filler material containing a pharmaceutical active ingredient, which may be salicylic acid, lactic acid, 5-fluoruracil, capsaicin, acetyl-salicylic acid, and nonoic acid vanillyl amide.

Additionally, the presently claimed invention pertains to an administration form for topical treatment of affected regions of the skin, for example, pimples or warts. It is submitted that such application would be readily apparent to one skilled in the art based on the particular aforementioned pharmaceutical active ingredients which are set forth in claim 1. The pharmaceutically active substances for the treatment of such disorders, which are set forth in claim 1, are provided herewith by their structural formulas on Appendix A. A review of the structural formulas reveals that the pharmaceutically active substances can be divided into three different groups. Group I are the acids, namely

salicylic acid, acetylsalicylic acid and lactic acid. These compounds are corrosive, keratinolytic and have antibacterial efficacy, all of which is known to the skilled artisan. 5-fluoruracil represents the second group. 5-fluoruracil is a chemotherapeutic agent that inhibits replication of cellular DNA. The third group of pharmaceutically active agents comprises capsaicin and nonoic acid vanillyl amide, a synthetic capsaicin derivative. These compounds are strong irritants which improve local blood circulation. They also have antibacterial and fungicidal activity. Their topical use might cause a painful and could be presumed as a local increase of temperature.

Although the three groups of active ingredients consist of chemically distinct members, it becomes evident that all these pharmaceutically active ingredients are potentially harmful. Therefore, they clearly should only be applied to those regions of the skin where their therapeutic efficacy is required, and adjacent regions of the skin should be protected from becoming contaminated or otherwise coming into contact with the pharmaceutically active ingredients to prevent these healthy regions from being affected by the severe side effects of these drugs. In turn, the pharmaceutically active ingredients that are set forth in claim 1 are not an arbitrary selection, but rather they are all drugs for topical administration wherein their application should be restricted to the affected region of the skin. This is so, in particular, because the filler material containing the pharmaceutically active ingredient and to be placed into the cut-out is not solid (as set forth in claim 6).

The presently claimed invention provides an administration form for these topically administrable drugs, the administration form being an adhesive die-cut article having an external contour and an internal cut-out whose contour is congruent with the

external contour of the article, wherein the matrix layer of the die-cut article consists of a compacted material. The use of a compacted material restricts the presence of the drug to the region of the internal cut-out. Thereby, migration of the drug from the desired site of action is avoided since the drug would migrate through the pores of a foam or through the mesh of a woven textile, if a product according to Kreckel, et al. would be employed. With respect to a "compacted material," it is respectfully maintained that one skilled in the art would readily be aware what constitutes a compacted material and would choose the appropriate compacted material based on the particular pharmaceutically active ingredient since it is apparent that the acids have different chemical properties than fluorouracil or capsaicin. Therefore, it is respectfully submitted that specifying the exact nature of the compacted material is not necessary since it would be clearly evident to one skilled in the art.

Regarding the Examiner's discussion of the subject matter of claim 9, it is submitted that the subject matter of claim 9 was not incorporated in its entirety into claim 1 upon specifying in claim 1 that the matrix is present as a compacted material for clarification purposes. Claim 9 specified that the compacted material is selected from the group of a foam, a fabric, a porous sheet or a non-woven fabric. However, these latter materials, as such, are not compacted materials *per se*, but rather may be selected to become a compacted material that would be suitable for realization of the present invention (i.e., the compacted material may be based on a foam, fabric, porous sheet or non-woven fabric). Nevertheless, it is submitted that one skilled in the art would understand what constitutes a compacted material in the context of the present invention.

At page 5 of the Examiner's Answer, the Examiner states that "compacted material" is indefinite, and therefore one example of a compacted material could be crushed steel, which is a type of compacted material. The Applicants submit that the present invention pertains to medicinal products, i.e., to products for topical administration of certain pharmaceutically active ingredients to the human skin. In other words, one skilled in the art would clearly recognize that the compacted material for the claimed die-cut article would be limited to those compacted materials which are pharmaceutically acceptable materials and which are approved for their reliability and security in pharmaceutical use. In other words, it would be clear to one skilled in the art that not just any compacted material may be employed, but rather compacted materials which pertain to the technical field to which the present invention pertains are employable. Within this scope, it is merely little experimentation for the skilled artisan to choose the appropriate compacted material for a given pharmaceutically active ingredient to realize the die-cut article of the claimed invention.

In summary, the Applicants respectfully submit that the pending claims provide a clear and unambiguous teaching to one skilled in the art for creating an adhesive die-cut article for administration of any one of the pharmaceutically active agents that are specified in claim 1 (and which are not an arbitrary selection) and that the selection of the appropriate compacted material would further be clear and unambiguous to one skilled in the art.

SUMMARY

The Applicant respectfully submits that the cited references do not teach, suggest or show the present invention as presently claimed or advantages attendant thereto. In

conclusion it is requested that the rejection of claims 1-8 as failing to comply with the enablement requirement, as failing to particularly point out the intended invention and as being unpatentable over U.S. Patent No. 5,244,677 (Kreckel, *et al.*) under 35 U.S.C. §103(a) be withdrawn, that the Board reverse the decision of the Examiner and allow claims 1-8.

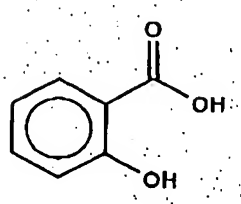
Respectfully submitted,

Date: July 1, 2007

By: _____
D. Peter Hochberg
Reg. No. 24,603

D. Peter Hochberg Co., L.P.A.
The Baker Building – 6th Floor
1940 E. 6th Street
Cleveland, Ohio 44114
(216) 771-3800

Structural formulas of the pharmaceutically active ingredients that may be present in a die-cut article according to U.S. patent application no. 10/670,046



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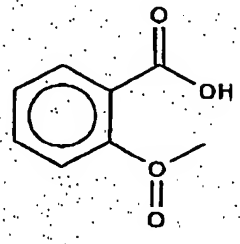

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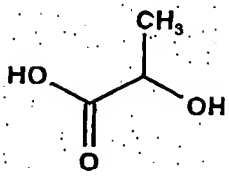

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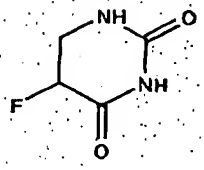

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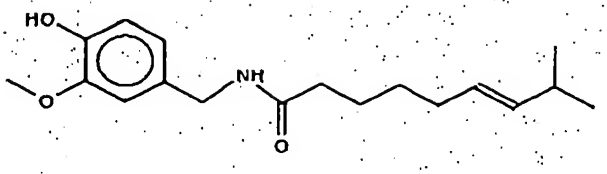
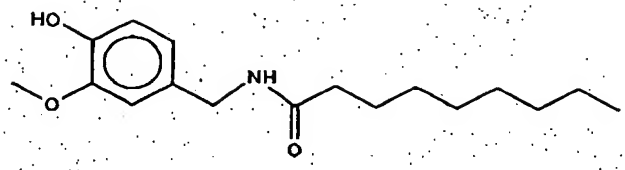


capsaicin



nonoic acid vanillyl amide